IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Power *et al.*

Patent No.: 7,638,480	Confirmation No.: 6247
Issued: December 29, 2009	Art Unit: 1647
For: USE OF OSTEOPROTEGERIN FOR THE TREATMENT AND/OR PREVENTION OF FIBROTIC DISEASE	Examiner: R. M. Deberry

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT

UNDER 37 CFR 1.705(d)

MS Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In accordance with 37 CFR §1.705(d), Patentee hereby requests reconsideration of the patent term adjustment indicated in the abovementioned application as issued. At issue, the patent was granted a 715 day patent term adjustment; however, as discussed below, Patentee asserts that an additional 364 days of patent term should be added. Patentee believes that the Office erred in (1) counting the "overlap" period as described in *Wyeth v. Kappos*, ___ F.3d ___ (Fed. Cir., Jan. 7, 2010) and (2) beginning the 3 year pendency period with the date under 35 C.F.R. § 371(c) instead of the date under 35 C.F.R. 371(b). Patentee believes that the correct patent term adjustment is 1062 days. Patentee respectfully requests review and reconsideration.

In accordance with 37 CFR §§1.705(d) and 1.705(b)(2), the following is a summary of the relevant patent term adjustment events as of the date of issue:

o   The application fulfilled the requirements of 35 U.S.C. § 371 on June 20, 2005; however, a first action, a Restriction Requirement, was not issued until July 31, 2007 (PTO delay of 345 days; 37 CFR §1.703(a)(1)).

o   A response to the Restriction Requirement was filed August 31, 2007, however, an Information Disclosure Statement was filed September 4, 2007 (Applicant delay of 4 days; 37 CFR §1.704(b)).

o   A non-final Office Action was issued on November 7, 2007, and a response to the Office Action was received on May 7, 2008 (Applicant delay of 90 days; 37 CFR §1.704(b)).

o   A second non-final Office Action was issued on October 14, 2008, which is more than four months after receipt of Applicants' May 7, 2008 response (PTO delay of 37 days; 37 CFR §1.703(a)(3)).

o   The patent issued on December 29, 2009 (811 days of pendency beyond three years from the date the national stage of the application commenced under 35 U.S.C. § 371(b), October 10, 2004 (PTO delay of 811 days; 37 CFR §1.702(b)).

Pursuant to *Wyeth v. Kappos*, ___ F.3d ___ (Fed. Cir., Jan. 7, 2010), periods of time only "overlap" in the context of calculation of patent term adjustment when the relevant periods of actual delay have at least one day in common. Accordingly, a delay attributable to failure of the USPTO to issue a first action within fourteen months but within the first three years after filing and a delay in patent issuance beyond three years from the date the national stage of the application commenced under 35 U.S.C. § 371(b) do not overlap.

With regard to the patent term adjustment awarded in the abovementioned application, Patentee asserts that the USPTO properly awarded the patent term adjustment due as a result of the pendency of the application beyond three years from the filing date, less the two instances of applicant delay detailed above (715 days). Patentee further acknowledges that the USPTO properly excluded from its calculation the instances of PTO delay that actually overlaps with the 811 days of

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pendency beyond three years from the filing of the application (the 37 days of PTO delay that occurred when the second non-final Office Action was mailed more than four months after receipt of Patentee's May 7, 2008 response).

However, Patentee assert that in awarding only 715 days in total, the USPTO apparently erroneously counted the 345 days of USPTO delay for issuance of a first action as overlapping with the 811 days of pendency beyond the three year period. In fact, these periods did not overlap. In addition, the USPTO apparently erroneously did not begin the three year pendency period until completion of the requirements under 35 U.S.C. § 371, rather than on the date that the national stage commenced under 35 U.S.C. § 371(b) (see the Decision from the Office of Petitions dated June 16, 2009 for U.S. Patent No. 7,465,444. Accordingly, Patentee asserts that 364 days of additional patent term, for a total of 1062 days, should be awarded in view of *Wyeth* and further in view of the failure to issue a patent within the three year pendency limit, based upon the date the national stage of the application commenced under 35 U.S.C. § 371(b).

Because Patentee's Request for Reconsideration of Patent Term Adjustment is not <u>solely</u> in view of *Wyeth*, Patentee has not filed a separate form PTO/SB/131 to request recalculation. As described in detail above, Patentee's request is based both on *Wyeth* and on using the proper 371(b) date instead of the 371(c) date to begin the 3 year pendency period for the application. The Office is respectfully requested to contact the undersigned if the Office believes that the form PTO/SB/131 is appropriate under the circumstances described in this paper.

Patentee notes for the record and in compliance with 37 CFR §§1.705(d) and 1.705(b)(2)(iii) that this patent is not subject to a terminal disclaimer. In accordance with 37 CFR §§1.705(d) and 1.705(b)(1), the fee set forth under 37 CFR §1.18(e) for filing this petition is provided for herewith.

CONCLUSION

Patentee believes no fee is due with this request, aside from the fee under 37 CFR 1.18(e). However, if an additional fee is due, please charge our Deposit Account No. 18-1945, from which the undersigned is authorized to draw, under Order No. SLII-P01-001.

Dated: <u>February 9, 2010</u>   Respectfully submitted,

By <u>/Jesse A. Fecker/</u>
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